

## **REMARKS**

Entry of this Amendment is proper under 37 C.F.R. § 1.116, because the Amendment places the application in condition for allowance for the reasons discussed herein; is not believed to raise any new issue requiring further search and/or consideration, because the amendments amplify issues previously discussed throughout prosecution; does not present any additional claims; and places the application in better form for an appeal should an appeal be necessary. The Amendment is necessary and was not earlier presented, because it is made in response to arguments raised in the final rejection and as discussed during the interview with the Examiner. Entry of the Amendment, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.116, are thus respectfully requested.

### **1. Status of the Claims**

Claims 1-50 stand pending; claims 10-46 stand withdrawn as directed to unelected subject matter. After entry of the present amendment, claims 2-9, 33, and 47-50 are canceled. The subject matter is canceled without prejudice to or disclaimer of the subject matter contained therein. Applicants reserve the right to file a continuation application on the canceled subject matter.

### **2. Support for the Amendments**

The amendment to claim 1 to replace “industrial yeast” with “beer yeast” is supported throughout the specification. For example, the phrase “beer yeast” is found in original claim 9 and at page 13, lines 24-27.

Claim 1 is further amended to add that the amino acid sequence encoded by an *S. cerevisiae* gene is particularly encoded by a *S. cerevisiae* strain S288C gene. Support for this amendment can be found, for example, at page 18, lines 6-15, of the specification (emphasis added):

FIG. 5 shows the result of DNA microarray-based comparative genomic hybridization. The genomic DNA of strain 34/70 was hybridized to a DNA microarray (Affymetrix Gene Chip Yeast Genome S98 Array) and the signal of each ORF (open reading frame) *was normalized to that of the*

*haploid strain S288C* and shown as Signal Log Ratio (2<sup>n</sup>). Signal Log Ratios were lined following genes order in Chromosome XVI. The non-Sc type genes do not hybridize to this Sc type array, therefore, the points (indicated by arrows) where the Signal Log Ratios show vigorous changes were considered to be translocation sites.

Thus, no prohibited new matter is believed to be included by entry of these amendments.

**3. Statement of the Substance of an Interview**

Applicants appreciate the courtesies extended to Applicants' counsel by Examiner Martinell in a telephone interview on January 8, 2008. The participants discussed the pending rejection of claims 1-9, 33, and 47-50 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The substance of the interview is incorporated into Applicants' response to that rejection below.

**4. Claim Objection**

The Office objects to Claim 50 for informalities. Applicants cancel Claim 50. The objection is thus moot. Applicants respectfully request withdrawal of the objection.

**5. Rejection under 35 U.S.C. § 112, Second Paragraph**

The Office rejects Claims 2-7, 33, and 47-50 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicants have canceled claim 2-7, 33, and 47-50 thereby mooting the rejection. Applicants respectfully request withdrawal of the rejection.

**6. Rejection under 35 U.S.C. § 112, First Paragraph**

The Office rejects Claims 1-9, 33, and 47-50 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office alleges that (1) the claim limitations at issue are the nucleic acids mentioned in Claim 1, and (2) the nucleic acids mentioned in Claim 1 "do not recite sufficient structure for one of skill in the art to determine whether applicants were in possession of the claimed invention at the time the application was filed." Office Action, paragraph bridging page 3-4.

Applicants traverse the rejection to the extent it applied to the claims as amended. Applicants have canceled claims 2-9, 33, and 47-50, thus the rejection with regard to these

claims stands mooted. The rejection to these claims is thus moot, and Applicants respectfully request withdrawal of the rejection.

To the extent the rejection applied to claims 1 and 8 as amended, Applicants provide the following arguments. The objective standard for written description is whether the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed. *See* M.P.E.P. § 2163.02 (citing *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989)). Applicants had possession of the claimed invention. Claim 1 provides for a method of screening for selected genes of a beer yeast by (a) comparing polynucleotide sequences of a beer yeast to genes of *Saccharomyces cerevisiae*, (b) selecting a polynucleotide sequence of the beer yeast encoding an amino acid sequence having 70% to 97% identity to an amino acid sequence encoded by an *S. cerevisiae* strain S288C\_gene; and (c) determining the function of the selected gene.

The *S. cerevisiae* genome and the polypeptides encoded by that genome were known at the time and been registered in a genomic database since 1998. *See, e.g.*, <http://www.yeastgenome.org/>. The reference sequence of *S. cerevisiae* is compared to the test nucleic acids and analyzed based on sequence to identify those which are similar to the protein sequence of target proteins (which were known) in *S. cerevisiae*. The ability to compare nucleic acids with selected genes from the *S. cerevisiae* was known at the time, as well as the ability to determine the function of the identified gene. As the reagents and means were in possession of the skilled artisan at the time, the claims have sufficient written description.

During the interview on January 8, 2008, the Office contended that multiple strains of *S. cerevisiae* exist, so that more than one reference genome is extant. The Office alleged that the requirement for knowledge of a reference genome for practice of the claimed method would require, for example, a properly disclosed *S. cerevisiae* strain from which the reference genome was obtained. The specification provides this disclosure. The specification discloses comparing polynucleotide sequences from a test strain with a polynucleotide sequence from *S. cerevisiae* strain S288C, for example. *See, e.g.*, Specification, page 18, lines 6-15. One of the ways that this comparison can be made is by hybridizing the test polynucleotide sequences to an Affymetrix GeneChip<sup>®</sup> Yeast Genome S98 Array, for example. *See, e.g., id.* This particular array is one example of an array containing “probes for all known 6,400 yeast genes” corresponding to *S. cerevisiae* strain S288C. *See, e.g.*, NCBI, GEO Accession No.

GPL90, at <http://www.ncbi.nlm.nih.gov/projects/geo/>, attached as **Exhibit 1**. The specification thus properly discloses a *S. cerevisiae* strain S288C from which the reference genome can be obtained.

The specification likewise provides an adequate written description of a polynucleotide sequence of a beer yeast encoding an amino acid sequence having 70 to 97% identity to an amino acid sequence encoded by an *S. cerevisiae* strain S288C gene. The Federal Circuit held that a polynucleotide may be adequately described by its ability to hybridize at high stringency to a reference gene having a known structure, based on the principle that the two sequences would share structural similarity:

The PTO has also provided a contrasting example of genus claims to nucleic acids based on their hybridization properties, and has determined that such claims may be adequately described if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar.

*Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 U.S.P.Q.2d 1609, 1615 (Fed. Cir. 2002) (citing with approval Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001), Example 9 at 35-37). In the present case, rather than defining structural similarity in terms of “stringent hybridization,” the claims recite that the polynucleotide sequence of the beer yeast has 70 to 97% identity to the reference sequence. Following the reasoning provided in the Guidelines, which was cited with approval by the Federal Circuit, the specification adequately describes a polynucleotide sequence of a beer yeast encoding an amino acid sequence having 70 to 97% identity to an amino acid sequence encoded by an *S. cerevisiae* strain S288C gene.

For each of the foregoing reasons, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

### **CONCLUSION**

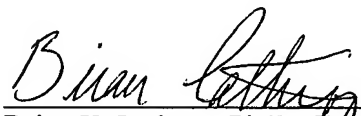
In view of the foregoing, Applicants respectfully request the entry of the amendments to place the application in condition for allowance, or in the alternative, in better form for appeal.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is respectfully requested and the fee should also be charged to our Deposit Account. If an Appeal Fee is required to maintain pendency of the present application, the Office is authorized to charge the Appeal Fee and use this paper as a Notice of Appeal.

If any matters remain outstanding, the Examiner is invited to contact the undersigned representative regarding this matter.

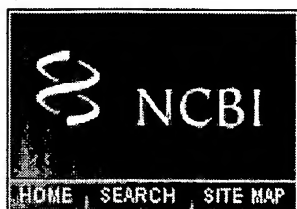
Respectfully submitted,

Date: February 1, 2008

  
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Attorney Docket No.: 47635-0002-00-US  
Application No. 10/791,791  
Office Action Dated: August 2, 2007  
Reply Dated: February 1, 2008

## **EXHIBIT 1**

[Handout](#) | [NAR 2006 Paper](#) |[NCBI](#) > [GEO](#) > **Accession Display** [?](#)Scope:  ☒ Format:  ☒ Amount:  ☒ GEO accession:  **Platform GPL90**

Query DataSets for GPL90

Status Public on Mar 11, 2002  
Title Affymetrix GeneChip Yeast Genome S98 Array YG-S98  
Technology type in situ oligonucleotide  
Distribution commercial  
Organism(s) Saccharomyces cerevisiae  
Manufacturer Affymetrix  
Manufacture protocol see manufacturer's web site

Description Has 9335 entries and was indexed 29-Jan-2002.  
Contains probes for all known 6,400 yeast genes, and candidate open reading frames. Based primarily upon the December 1998 version of the Saccharomyces Genome Database (SGD).  
Corresponds to strain S288C.

Keywords = high density oligonucleotide array

Web link <http://www.affymetrix.com/support/technical/byproduct.affx?product=yeast>  
<http://www.affymetrix.com/analysis/index.affx>

Submission date Feb 19, 2002  
Organization Affymetrix, Inc.  
E-mail(s) [geo@ncbi.nlm.nih.gov](mailto:geo@ncbi.nlm.nih.gov), [support@affymetrix.com](mailto:support@affymetrix.com)  
Phone 888-362-2447  
URL <http://www.affymetrix.com/index.affx>

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City Santa Clara  
State/province CA  
ZIP/Postal code 95051  
Country USA

Samples (1091) GSM6219, GSM6220, GSM6221, GSM6222, GSM6223, GSM6224

[⌵ Show all...](#)

Series (88) GSE423 Yeast aging study

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GSE441 Yeast glucosamine treatment

GSE461 Response to LiCl of galactose grown cells

**Data table header descriptions**

<b>ID</b>	Affymetrix Probe Set ID
<b>ORF</b>	Entrez Gene Link
<b>SPOT_ID</b>	identifies controls
<b>Species Scientific Name</b>	The genus and species of the organism represented by the probe set.
<b>Annotation Date</b>	The date that the annotations for this probe array were last updated. It will generally be earlier than the date when the annotations were posted on the Affymetrix web site.
<b>Sequence Type</b>	
<b>Sequence Source</b>	The database from which the sequence used to design this probe set was taken.
<b>Target Description</b>	GenBank description associated with the representative public identifier. Blank for some probe sets.
<b>Representative Public ID</b>	The accession number of a representative sequence. Note that for consensus-based probe sets, the representative sequence is only one of several sequences (sequence sub-clusters) used to build the consensus sequence and it is not directly used to derive the probe sequences. The representative sequence is chosen during array design as a sequence that is best associated with the transcribed region being interrogated by the probe set. Refer to the Sequence Source field to determine the database used.
<b>Gene Title</b>	Title of Gene represented by the probe set.
<b>Gene Symbol</b>	A gene symbol, when one is available (from UniGene).
<b>ENTREZ_GENE_ID</b>	Entrez Gene Database UID
<b>RefSeq Transcript ID</b>	
<b>Gene Ontology Biological Process</b>	Gene Ontology Consortium Biological Process derived from LocusLink. Each annotation consists of three parts: Accession Number // Description // Evidence. The description corresponds directly to the GO ID. The evidence can be direct, or extended.
<b>Gene Ontology Cellular Component</b>	Gene Ontology Consortium Cellular Component derived from LocusLink. Each annotation consists of three parts: Accession Number // Description // Evidence. The description corresponds directly to the GO ID. The evidence can be direct, or extended.
<b>Gene Ontology Molecular Function</b>	Gene Ontology Consortium Molecular Function derived from LocusLink. Each annotation consists of three parts: Accession Number // Description // Evidence. The description corresponds directly to the GO ID. The evidence can be direct, or extended.



**Data table**

ID	ORF	SPOT_ID	Species Scientific Name	Annotation Date	Sequence Type	Sequence
10000_at	YLR331C		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10001_at	YLR332W		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10002_i_at	YLR333C		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10003_f_at	YLR333C		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10004_at	YLR334C		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10005_at	YLR335W		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10006_at	YLR336C		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10007_at	YLR337C		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10008_at	YLR338W		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10009_at	YLR339C		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10010_at	YLR295C		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10011_at	YLR296W		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10012_at	YLR297W		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10013_at	YLR298C		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10014_at	YLR299W		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10015_at	YLR300W		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10016_at	YLR301W		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy
10017_at	YLR302C		Saccharomyces cerevisiae	"Jul 11, 2007"	Exemplar sequence	Saccharomy

Total number of rows: **9335**Table truncated, full table size **8057 Kbytes**.[View full table...](#)[Annotation SOFT table...](#)**Download family**

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